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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,258	12/21/2001	Carsten Schelp	05552.1450	5022

22852 7590 07/29/2005

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

Deborah A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22 in the reply filed on May 2, 2005 is acknowledged. The traversal is on the ground(s) that the examiner has failed to establish that the search and examination of the entire application constitutes a serious burden because Group I and Group II are classified in the same class and that the examination of Group II will overlap with the examination of Group I. This is not found persuasive because classification is merely one indication of the burdensome nature of the search involved. Further, classification in the restriction are illustrative only and do not represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

With respect to applicant's request to rejoin the kit claims if the methods if either or both of Groups I and II are found allowable, the examiner will consider all requests of the applicant.

The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement filed April 3, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on December 22, 2000. It is noted, however, that applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1, recites that R1 is associated with a solid phase, R2 is associated with label L1 and R3 is associated with label L2 is vague, because it

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is unclear as to whether these reagents are bound to the solid phase and labels or if they are just associated by incubation of reagents.

7. Claims 1 and 19 recites that R2 takes place at a higher analyte A concentration, at a later time in the incubation, or at a higher analyte A concentration and at a later time in the incubation. This limitation is confusing because of its redundancy.

8. Claims 5, 6 and 19 are vague because the association between binding partner R3 and a member X and the label L2 is unclear. Does R3 bind L2 or a member of X or both? Does L2 bind to a member of X or member Y? The binding relationship of the above mentioned reagents are unclear.

9. Claim 17 recites that the interaction of claim 1 comprises an energy transfer is vague because it is unclear from which reactants this energy transfer is directed from.

10. Claim 8 is vague because it recites that R1, R2 and R3 can be the same binding partner, which is confusing because it is unclear as to whether this means they are all polyclonal, monoclonal or all are the same binding entity. The claim is unclear as to what is meant by the same binding partner.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 7-12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragle et al (USP#4,595,661).

The claims are broadly drawn to a method for detecting an analyte A in a sample comprising incubation of a sample with an analyte binding partner R1 associated with a solid support, R2 associated with a label L1 and R3 associated with label L2 wherein saturation of analyte A-binding sites of the R2 binding partner takes place at a higher analyte A concentration at a later time in the incubation than does saturation of analyte A-binding sites of the R3 binding partner and determining and L1-dependent measurement signal at a different time from and L2-dependent measurement signal or an L1 plus L2-dependent measurement signal.

The reference of Cragle teaches an immunoassay for assaying antigenic substance (Ag) in a fluid sample. The fluid sample is contacted with binding entities selected from different types of antibodies. Whereas one embodiment a fluid sample is contacted with L-Aba, which is R2 associated with L1 and Abb-Sc, which is R1 associated with a solid support. After the complex of L-Aba-Ag-Abb-SC is formed, the unreacted L-Aba is measured. An additional entity is then added to the fluid sample, L-Abc, which is R3 associated with a label L3 and is present in an amount to avoid the hook effect. Cragle et al teaches that the additional entity L-Abc has as constant (K) for the Ag that is lower than the K of its corresponding first entity, which is L-Aba for the Ag. Therefore, the saturation

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of analyte A- binding sites of the first entity, L-Aba, which is R2 associated with L1, would have higher analyte A concentration than that of L-Abc, which is R3 associated with a label L3 (abstract, column 2, lines 55-65 and column 3, lines 1-65). The assay method can be a one or two step sandwich (column 1, lines 42-68), which examiner interprets as being heterogeneous or homogeneous. The binding entities can be all polyclonal or monoclonal in nature (column 5, lines 1-15). The labels on the binding entities can be radioactive tags, fluorescent labels and enzyme labels, wherein both L-Aba and L-Abc appear to have the same type of label (column 1, lines 55-68). The solid phase of Abb-Sc, can be polystyrene beads which are microparticles and can function as a label for detection.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al in view of a second reference by Cragle (USP#4,590,169).

The teachings of the first reference of Cragle are set forth above, but is silent with respect to the binding entity R2 associated with a suspendable solid phase.

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However, the second reference of Cragle teaches that binding entities use particles for direct particle agglutination assays, wherein the particles become aggregated if the antigen is in the sample and this protocol can be performed in one step.

It would have been obvious to one of ordinary skill in the art to include the use of suspendable beads in an assay system taught in the second reference of Cragle because they are useful in agglutination assays. One of ordinary skill would be motivated to do so because particle agglutination can be performed in a one step, eliminating the need for separation of reagents.

15. Claims 5,6, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al in view of Marquardt et al (USP#6,610,494).

The teachings of Cargle et al are set forth above but sole difference appears to be that is does not teach an additional labeling system such as an XY binding pair.

However, the reference of Marquardt et al teaches an XY binding pair such as biotin-avidin (or streptavidin) labeling system that is used for indirect measurement of an analyte by measuring the label (column 7, lines 35-50). With respect to the relationship of the L1-depdent measurement signals determined at time T1 and the L2 –dependent measurement signal being determined at time T2, with T1 being earlier than T2 is taught by the primary reference of Cragle et al . Cragle teaches an embodiment wherein the sample is contacted with L-Aba (R2) associated with label L1 and Abb-Sc (R1) associated with a solid support is

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incubated to form a complexed and measured. This is the first measurement signal represents time T1. An additional entity L-Abc (R3) associated with label L3 is added to the mixture in an amount to avoid the hook effect (abstract, column 2, lines 55-65 and column 3, lines 1-65). The examiner interprets this as the second measurement signal time T2, which measurement is later than that of T1 which makes T1 measurement earlier than that of T2.

It would have been obvious to one of ordinary skill in the art to include the use of an XY binding system as in avidin-biotin or (streptavidin) because they are stable under the conditions of an assay, are specific and have low background values that do not interfere with the assay. One would be motivated to use this system because they give the assay greater sensitivity.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al in view of Pitner et al (USP#5,641,629).

The teaching of Pitner et al are set forth above, but is silent with respect to energy transfer.

The reference of Pitner et al teaches that energy transfer techniques offers a sensitive and simple method of measuring the binding of specific analytes or target molecules. The method permits qualitative and quantitative binding measurements (column 4, lines 58-67).

Therefore, it would have been obvious to one of ordinary skill in the art to use energy transfer techniques as taught by Pitner et al because of its sensitivity and simplicity in measuring of analytes.

Conclusion

Allowable Subject Matter

17. Claim 18 is allowed.

18. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor suggests a signal forming system that involves photosensitizers associated with microparticles and chemiluminescent substances associated with microparticles..

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A. Hevey et al teaches methods for the detection and determination of ligands (USP#4,228,237)

B. Watts et al teaches a heterogeneous binding assay (USP#5,437,983)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

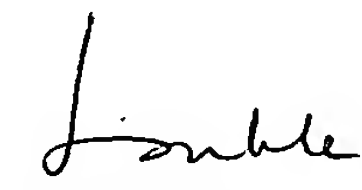
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 8, 2005



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07/24/05